No Cost Extension for SCEDDBO Marie Lynn Miranda to: Richard Callan, Nica Louie 03/19/2012 07:11 AM

Richard Auten, Kathryn Crary, Klugh Jordan, "Pamela Maxson Ph. D." Show Details

History: This message has been replied to.

Dear Rich,

Attached please find a no-cost extension request for SCEDDBO. We appreciate your consideration of this request.

Regards,

mlm

Marie Lynn Miranda, Ph.D.
Professor and Dean, School of Natural Resources and Environment
Director, Children's Environmental Health Initiative
Professor, Department of Pediatrics
440 Church Street
2046 Dana Building
Ann Arbor, MI 48109
734.764.2550
mlmirand@umich.edu





Re: SCEDDBO/Miranda Proposal (UM Ref. 12-PAF01535) -- EPA STAR

Grant RD83329301 (Duke University) Richard Callan to: Anthony Nielsen

03/21/2012 05:26 PM

Cc: Elaine Brock, Kathryn Crary, mimirand

Bcc: Richard Callan

Follow Up:

Normal Priority. Follow up on 03/22/2012 at 09:00 AM.



Hi Tony,

Thank you for following up. The justification and budget for the subaward was sent earlier but according to our Grants and Interagency Agreement Management Division (GIAMD) we also need a revised budget for the total project, showing the UM subaward as a portion of the overall budget for the SCEDDBO Center at Duke. I have included a message from the Grants Specialist pertaining to this below.

It would be helpful if you could include the EPA STAR Grant number RD83329301 on future correspondence and forms and also include a signature page with the new package.

Thank you for your help with this. Please let me know if you have any questions.

Best regards,

Rich



Duke RD833293 UM Subaward revised 022812.pdf

---- Forwarded by Richard Callan/DC/USEPA/US on 03/21/2012 03:33 PM -----

From:

Joselynn Hawkins/DC/USEPA/US

To:

Richard Callan/DC/USEPA/US@EPA

Cc:

Jennifer Robbins/DC/USEPA/US@EPA, Roberto Perez/DC/USEPA/US@EPA

Date:

02/29/2012 09:18 AM

Subject:

Re: New Subaward to University of Michigan for Duke University Children's Center

(RD83329301/Miranda)

Hi Richard.

I will have to process a budget revision in order to incorporate the changes, so I need a revised budget for the total project. It looks like the attached budget was just for the subaward. Also, can you please submit a change request for a budget revision in IGMS.

Thanks.

Joselynn Hawkins, Grants Specialist U.S. EPA, OARM, GAD 1200 Pennsylvania Avenue, N.W. 3903R Washington, D.C. 20460

Phone: 202-564-5305 Fax: 202-565-3082

Rich Callan, MPH

Environmental Health Scientist
Health Research and Fellowships Division
National Center for Environmental Research
U.S. Environmental Protection Agency
Phone: 703-347-8051 Fax: 703-347-8140

Office Address for FedEx, Express Mail or Courier: US EPA, 2777 South Crystal Drive (Potomac Yard One), Room S-11937, Arlington, VA 22202 Mailing Address (can take a month for delivery): 1200 Pennsylvania Avenue NW, Mail Code 8723P, Washington, D.C. 20460-0001

National Center for Environmental Research http://www.epa.gov/ncer/

Anthony Nielsen

Hi Richard, I was just following up on the status...

03/21/2012 10:57:23 AM

From:

Anthony Nielsen <Anielsen@umich.edu> Richard Callan/DC/USEPA/US@EPA

To: Cc:

Kathryn Crary <kcrary@umich.edu>, mimirand@umich.edu, Elaine Brock <ebrock@umich.edu>

Date:

03/21/2012 10:57 AM

Subject:

Re: SCEDDBO/Miranda Proposal (UM Ref. 12-PAF01535)

Hi Richard,

I was just following up on the status of this proposal originally submitted by The University of Michigan in January, with a revision submitted in February. Any updates would be appreciated.

Sincerely, Tony

Anthony L. Nielsen, J.D., B.S.B.A.
Project Representative
Office of Research and Sponsored Projects
Wolverine Tower
First Floor, Room 1070
3003 South State Street
Ann Arbor, MI 48109-1274
Phone 734.936.0401
Fax 734.763.4053

Assistant: Andrea Mucci muccia@umich.edu 734-647-1458



Re: New Subaward to University of Michigan for Duke University Children's Center (RD83329301/Miranda)

Richard Callan to: Joselynn Hawkins

04/03/2012 06:51 PM

Jennifer Robbins, Roberto Perez, "Pamela Maxson, Ph.D.",

"Miranda, Marie Lynn"

Hi Joselynn,

OK that sounds good, thank you. I will consult with you separately to find out what to put into the CR so that you can process both at once.

I have submitted a draft of the NCE to Roberto P. in our office to see there are any issues we'll need to address before submitting the final version for SRO approval.

I have transmitted your request to Duke to prepare a revised SF-424A with the new totals for each budget category along with a separate SF424A for the subaward to the University of Michigan.

Thank you.

Rich

Rich Callan, MPH Environmental Health Scientist Health Research and Fellowships Division National Center for Environmental Research U.S. Environmental Protection Agency Phone: 703-347-8051 Fax: 703-347-8140

Joselynn Hawkins

Hi Richard, I can process both the NCE and the...

03/29/2012 10:25:45 AM

From:

Joselynn Hawkins/DC/USEPA/US

To: Cc: Richard Callan/DC/USEPA/US@EPA

Jennifer Robbins/DC/USEPA/US@EPA, Roberto Perez/DC/USEPA/US@EPA, "Pamela Maxson, Ph.D." <pamela.maxson@duke.edu>, "Miranda, Marie Lynn" <mlmirand@umich.edu>

Date:

03/29/2012 10:25 AM

Subject:

Re: New Subaward to University of Michigan for Duke University Children's Center

(RD83329301/Miranda)

Hi Richard,

I can process both the NCE and the Budget revision at the same time with one CR. Since the NCE will extend the project beyond 5 years, please make sure to include the SRO approval on the CR.

Regarding the budget revision, I need a revised SF-424 for Duke's total budget that shows the new totals for each budget category. Even though the change is in year 5, we need the total budget so that I can update the award agreement as appropriate.

Please feel free to contact me if you have any questions.

Thanks.

Joselynn Hawkins, Grants Specialist U.S. EPA, OARM, GAD 1200 Pennsylvania Avenue, N.W. 3903R Washington, D.C. 20460 Phone: 202-564-5305

Fax: 202-565-3082

Richard Callan Joselynn Hawkins Hi Joselynn, I wanted to make sure to understan...

Hi Richard, I will have to process a budget revis...

03/27/2012 07:50:31 PM 02/29/2012 09:18:07 AM



Re: New Subaward to University of Michigan for Duke University Children's Center (RD83329301/Miranda)

Joselynn Hawkins to: Richard Callan

03/29/2012 10:25 AM

Cc: "Missards Maria Issuer"

"Miranda, Marie Lynn"

Hi Richard,

I can process both the NCE and the Budget revision at the same time with one CR. Since the NCE will extend the project beyond 5 years, please make sure to include the SRO approval on the CR.

Regarding the budget revision, I need a revised SF-424 for Duke's total budget that shows the new totals for each budget category. Even though the change is in year 5, we need the total budget so that I can update the award agreement as appropriate.

Please feel free to contact me if you have any questions.

Thanks,

Joselynn Hawkins, Grants Specialist U.S. EPA, OARM, GAD 1200 Pennsylvania Avenue, N.W. 3903R Washington, D.C. 20460

Phone: 202-564-5305 Fax: 202-565-3082

Richard Callan

Hi Joselynn, I wanted to make sure to understan...

03/27/2012 07:50:31 PM

From:

Richard Callan/DC/USEPA/US

To:

Joselynn Hawkins/DC/USEPA/US@EPA

Cc:

Jennifer Robbins/DC/USEPA/US@EPA, Roberto Perez/DC/USEPA/US@EPA, "Pamela Maxson,

Ph.D." <pamela.maxson@duke.edu>, "Miranda, Marie Lynn" <mlmirand@umich.edu>

Date:

03/27/2012 07:50 PM

Subject:

Re: New Subaward to University of Michigan for Duke University Children's Center

(RD83329301/Miranda)

Hi Joselynn,

I wanted to make sure to understand exactly what is needed. This change is just in Year 5 of the grant -- so then you would like to see the revised Year 5 budget for the Center, broken out into the EPA budget categories (Personnel, Fringe Benefits, Travel, etc.), with a separate budget in the same categories for the UM subaward, is that correct?

I've attached the total budget (direct costs only) from the grant proposal, as you can see it was revised before the award was made. I'm also attaching one of the SF424A forms in the file. I'm thinking you would like the budgets for both Duke and the UM subaward to be in this format. I am cc:'ing Pam Maxson at Duke as well so she is in the loop with what still needs to be provided.

For the Change Request, they have also requested a no-cost extension and since that needs to go through right away, I put in a CR for that first, so once that is completed we can work on the CR for the budget revision for the UM subaward, I hope that is OK.

Thank you!

Best regards,

Rich





Total revised_SCEDDBObudget(nf)_A_2007.pdf SF424 Duke Miranda Year 1.pdf

Rich Callan, MPH
Environmental Health Scientist
Health Research and Fellowships Division
National Center for Environmental Research
U.S. Environmental Protection Agency
Phone: 703-347-8051 Fax: 703-347-8140

Office Address for FedEx, Express Mail or Courier: US EPA, 2777 South Crystal Drive (Potomac Yard One), Room S-11937, Arlington, VA 22202 Mailing Address (can take a month for delivery): 1200 Pennsylvania Avenue NW, Mail Code 8723P, Washington, D.C. 20460-0001 National Center for Environmental Research http://www.epa.gov/ncer/

Joselynn Hawkins

Hi Richard, I will have to process a budget revis...

02/29/2012 09:18:07 AM



Re: Re: SCEDDBO transfer to UM



Joselynn Hawkins to: Kathryn Crary

> From: Richard Callan/DC/USEPA/US

Cc: Richard Callan, "Pamela Maxson, Ph.D.", pm12

04/18/2012 03:06 PM

I believe I have everything, but I'll know better once I process the action. Joselynn Hawkins, Grants Specialist U.S. EPA, OARM, GAD 1200 Pennsylvania Avenue, N.W. 3903R Washington, D.C. 20460 Phone: 202-564-5305 Fax: 202-565-3082 ----Kathryn Crary <kcrary@umich.edu> wrote: ----To: Joselynn Hawkins/DC/USEPA/US@EPA From: Kathryn Crary <kcrary@umich.edu> Date: 04/18/2012 02:51PM Cc: Richard Callan/DC/USEPA/US@EPA, "Pamela Maxson, Ph.D." <pamela.maxson@duke.edu>, pm12@duke.edu Subject: Re: Re: SCEDDBO transfer to UM Hi Joselynn, Just to confirm -- you don't need anything from the University of Michigan's sponsored research office at this point, correct? Thanks, Kate Kate Crary Grant Administrator School of Natural Resources and Environment University of Michigan 2038C Dana Building 440 Church Street Ann Arbor, MI 48109 (734)763-9925 On Wed, Apr 18, 2012 at 1:57 PM, Joselynn Hawkins < Hawkins.Joselynn@epamail.epa.gov> wrote: > Yes, the information is sufficient. > Joselynn Hawkins, Grants Specialist > U.S. EPA, OARM, GAD > 1200 Pennsylvania Avenue, N.W. 3903R > Washington, D.C. 20460 > Phone: 202-564-5305 > Fax: 202-565-3082 > ----Richard Callan/DC/USEPA/US wrote: ----> To: "Pamela Maxson, Ph.D." <pamela.maxson@duke.edu>, Joselynn > Hawkins/DC/USEPA/US@EPA

```
> Date: 04/18/2012 11:38AM
> Cc: kcrary@umich.edu, pm12@duke.edu
> Subject: Re: SCEDDBO transfer to UM
> Thank you, Pam! Joselynn, is this additional information sufficient for
> us to process the subaward?
> Best regards,
> Rich
      -----
> * From: *"Pamela Maxson, Ph.D." [pamela.maxson@duke.edu]
> * Sent: *04/18/2012 02:16 PM GMT
> * To: *Joselynn Hawkins; Richard Callan
> * Cc: *"kcrary@umich.edu" <kcrary@umich.edu>; "pml2@duke.edu" <
> pm12@duke.edu>
> * Subject: *SCEDDBO transfer to UM
> Hello,
> I have revised the budget according to suggestions. I have attached two
> forms of it, one SF_424a_Budget_form_total_both, has the original amount as
> well as the revised amount. The second form, SF_424a_Budget_form_total,
> includes only the revised amount, for ease of reading.
> Please let me know if there is anything else I can do for you. Thank you
> very much for your assistance in this process.
> Best,
>
> Pam
> Pamela J. Maxson, Ph.D., SPHR
> Research Director, Director of Human Resources
> Children's Environmental Health Initiative
> Box 90328, A137 LSRC
> Duke University
> (919) 812-8389
> pm12@duke.edu
```



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

MAY 1 5 2012

OFFICE OF RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: Request for Deviation from 40 CFR 40.125-1(b) to Extend the Duration of

Assistance Agreement RD83329301 Beyond Six Years

Title: Southern Center on Environmentally Driven Disparities in Birth Outcomes

Institution: Duke University

Principal Investigator: Marie Lynn Miranda

FROM:

E. Ramona Trovato

Senior Resource Official

Office of Research and Development (8101R)

TO:

Denise Polk, Director

National Policy, Training and Compliance Division

Office of Grants and Debarment (3903R)

I. Requirements

The purpose of this memorandum is to request approval for a deviation from 40 CFR Part 40.125-1(b). This deviation will allow grant RD83329301 with Duke University to be extended for two years at no cost. Both the project and budget periods for this assistance agreement are currently 05/01/2007 to 04/30/2012. The extension being requested would result in a seven-year duration with new project and budget periods of 05/01/2007 to 04/30/2014. This is expected to be the only extension of this assistance agreement's duration.

II. Background

This grant was awarded to Duke University as a result of a 2005 Science to Achieve Results (STAR) Request for Applications for Centers for Children's Environmental Health and Disease Prevention Research (CEHCs). Specific goals of the Duke University Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO) include: 1) to develop and operate an interdisciplinary children's health research center with a focus on understanding how biological, physiological, environmental, and social aspects of vulnerability contribute to health

disparities; 2) to enhance research in children's health at Duke by promoting research interactions among programs in biomedicine, environmental health, and the social sciences and establishing an infrastructure to support and extend interdisciplinary research; 3) to develop new methodologies for incorporating innovative statistical analysis into children's environmental health research and policy practice, with a particular emphasis on genetic and spatial analysis; 4) to serve as a technical and educational resource to the local community, region, the nation, and to international agencies in the area of children's health and health disparities; and 5) to translate the results of the Center into direct interventions in clinical care and practice.

The Southern Center on Environmentally-Driven Disparities in Birth Outcomes consists of 3 projects and 3 Cores. Research Project A is entitled "Mapping Disparities in Birth Outcomes," Research Project B is "Healthy Pregnancy, Healthy Baby: Studying Racial Disparities in Birth Outcomes" and Research Project C is "Perinatal Environmental Exposure Disparity and Neonatal Respiratory Health." The Center is organized around an Administrative Core, with a Geographic Information Systems and Statistical Analysis Core and a Community Outreach and Translation Core. Synergies and complementarities exist across all research projects and cores.

III. Purpose

The Duke University Children's Center is requesting a two-year no-cost extension from May 2012 to April 2014. The extension is necessary to allow the investigators under Project A to obtain 2010 birth record data, to analyze whether changes in the built environment are reflected in changing pregnancy outcomes, complete the geocoding of the data and complete data and statistical analysis. For Project B, the investigators need the additional time to complete data analysis and prepare manuscripts, connect the data with the psychosocial, genetic and physical health of mothers and infants in the clinical project, finish developing and validating statistical methods for genetic, clinical and environmental data interaction analysis, characterize the complex interactions between three categories of factors that might influence pregnancy outcomes (host, social and environmental contributors), compile results and disseminate information to the community. For Project C, additional time is needed for data analysis to determine the window of vulnerability for maternal inhalational exposure to particulate matter and diesel exhaust that may worsen the effects of postnatal ozone on airway hyperreactivity (asthma model) and on lung alveolar structure and to understand the nature of time-specific responses to environmentally relevant concentrations of diesel exhaust. Additional time is also needed to complete analyses on materials collected to assess effects of altered immune response pathways (host susceptibility) on postnatal lung structure and function. All of these analyses for the three projects were part of the original specific aims of the proposal. The Duke University Children's Center will not be able to complete all these analyses within a one-year timeframe so they have requested a two-year extension.

The remaining funds are sufficient to complete the work within the two-year extension period. NCER has determined that this extension is justified and will enable the recipient to complete the work as originally planned. The scope of work of the project has not changed and the project investigators have complied with the terms and conditions of the award agreement. The investigators have made significant progress to date but circumstances beyond their control have precipitated the need for additional time as described above. This study is producing results that will be useful to protect children's and maternal health, prevent adverse birth outcomes, and

better understand social	factors a	as well a	s gene	and	environment	interactions	important ir
children's health.							

IV. Recommendations

- 1. Approval of a deviation from 40 CFR Part 40.125-1(b) that would allow the project and budget periods for grant RD83329301 to be extended by two years.
- 2. A new project and budget period for grant RD83329201 of 05/01/2007 to 04/30/2014.

Office of Grants and Debarment Concurrence

Denise Polk, Director National Policy, Training and Compliance Division Office of Grants and Debarment (3903R) Date



Re: Urgent request -- Would you have a few short bullet points for key research results from SCEDDBO?

Marie Lynn Miranda

to:

Richard Callan 06/14/2012 09:50 PM

Cc:

Pam Maxson, Richard Auten

Hide Details

From: Marie Lynn Miranda <mlmirand@umich.edu>

To: Richard Callan/DC/USEPA/US@EPA

Cc: Pam Maxson <pamela.maxson@duke.edu>, Richard Auten <auten@duke.edu>

Security:

To ensure privacy, images from remote sites were prevented from downloading. Show Images

History: This message has been replied to and forwarded.

Hey Rich,

Here are three bullets:

- 1) Epidemiological evidence indicates that exposure to PM2.5 is associated with poorer birth outcomes even in areas that are in attainment with the National Ambient Air Quality Standard.
- 2) Depauperate built environments are associated with poorer birth outcomes.
- 3) Animal models show that the impact of air pollution on post-natal metabolism (which affects growth) is exacerbated by exposure to social stress.

I will be on the road tomorrow, but can be reached on cell if you have questions -- 919-218-1829.

Thanks for including us.

mlm

On Thu, Jun 14, 2012 at 7:31 PM, Richard Callan < Callan.Richard@epamail.epa.gov > wrote:

Hi Marie Lynn and Pam,

We received a request this afternoon for a summary fact sheet for the EPA Administrator on the Children's Centers program and would like to include 2-3 bullet points on key impacts/findings from the Duke/University of Michigan Children's Center. The fact sheet would be used to prepare the Administrator's talking points. If you have time for a quick call or could email 2-3 findings that could be shared, we would really appreciate it. The fact sheet is due early tomorrow morning and I apologize for this rushed request.

Thon	1	WO	
Than	n	yo	u,

Rich

Rich Callan, MPH
Environmental Health Scientist
Health Research and Fellowships Division
National Center for Environmental Research
U.S. Environmental Protection Agency
Phone: 703-347-8051 Fax: 703-347-8140

Office Address for FedEx, Express Mail or Courier: US EPA, 2777 South Crystal Drive (Potomac Yard One), Room S-11937, Arlington, VA 22202 Mailing Address (can take a month for delivery): 1200 Pennsylvania Avenue NW, Mail Code 8723P, Washington, D.C. 20460-0001 National Center for Environmental Research http://www.epa.gov/ncer/

Marie Lynn Miranda, Ph.D.
Professor and Dean, School of Natural Resources and Environment
Director, Children's Environmental Health Initiative
Professor, Department of Pediatrics
440 Church Street
2046 Dana Building
Ann Arbor, MI 48109
734.764.2550
mlmirand@umich.edu





SCEDDBO executive summary 2012 Pamela Maxson, Ph.D. to:

Richard Callan 11/30/2012 02:25 PM

Hide Details

From: "Pamela Maxson, Ph.D." <pamela.maxson@duke.edu>

To: Richard Callan/DC/USEPA/US@EPA

Follow Up:

Normal Priority. Follow up on 12/07/2012 at 09:00 AM.

History: This message has been replied to.

1 Attachment



SCEDDBO_2012_6_short.docx

Hi Rich,

I have attached the executive summary.

Be well,

Pam

Pamela J. Maxson, Ph.D., SPHR Research Director, Director of Human Resources Children's Environmental Health Initiative Box 90328, A137 LSRC **Duke University** (919) 812-8389 pm12@duke.edu

Richard Callan

To:

Callan, Richard

Subject:

Fw: SCEDDBO annual report

Date: Attachments: Friday, July 12, 2013 1:49:37 PM IRB NOTIFICATION OF CONTINUING REVIEW APPROVAL.docx

SCEDDBO 2012 5.docx 24N Auten Approval.pdf

DBR IRB.docx

---- Forwarded by Richard Callan/DC/USEPA/US on 07/12/2013 01:48 PM -----

From "Pamela Maxson, Ph.D."

To Richard Callan/DC/USEPA/US@EPA

Date: 11/30/2012 10:19 AM Subject SCEDDBO annual report

Hello Rich,

I hope you are doing well and that you had a very happy Thanksgiving. I have attached our annual report, our two IRB approvals, and the IACUC approval. I will send you the short version for the website this weekend after it is reviewed.

Thank you for all you do.

Pam

Pamela J. Maxson, Ph.D., SPHR Research Director, Director of Human Resources Children's Environmental Health Initiative Box 90328, A137 LSRC Duke University (919) 812-8389

pm12@duke.edu(See attached file: IRB NOTIFICATION OF CONTINUING REVIEW APPROVAL.docx)(See attached file: SCEDDBO_2012_5.docx)(See attached file: 24N Auten Approval.pdf)(See attached file: DBR_IRB.docx)

Davis, Sharon

To:

Callan, Richard

Subject:

FW: Race, socioeconomic status, and air pollution exposure in North Carolina (Environ Res.) -- Would you have a

.pdf?

Date: Attachments: Wednesday, July 17, 2013 3:13:01 PM 1-s2.0-S0013935113001138-main.pdf

A pdf of the article you requested from Dr. Miranda is attached.

Thanks, sharon

From: Marie Lynn Miranda [mailto:mlmirand@umich.edu]

Sent: Tuesday, July 16, 2013 9:16 PM

To: Davis, Sharon Cc: Callan, Richard

Subject: FW: Race, socioeconomic status, and air pollution exposure in North Carolina (Environ Res.) -- Would you

have a .pdf? Sharon,

Can you send this to Rich Callan, please?

mlm

From: Callan, Richard [mailto: Callan.Richard@epa.gov]

Sent: Tuesday, July 16, 2013 8:41 PM

To: Marie Lynn Miranda

Subject: Race, socioeconomic status, and air pollution exposure in North Carolina (Environ Res.) -- Would you have a

.pdf?

Hi Marie Lynn,

I was thinking it would be good for Jim's talk to reference the article that went online last week in Environmental Research (Gray, Edwards, Miranda) but at the moment we don't have online access to this journal. Could you possibly send a .pdf of this so Jim could reference it in his talk? Gray SC, Edwards SE, Miranda ML. Race, socioeconomic status, and air pollution exposure in North Carolina. Environ Res. 2013 Jul 11. pii: S0013-9351(13)00113-8. doi: 10.1016/j.envres.2013.06.005.

[Epub ahead of print]

http://www.journals.elsevier.com/environmental-research/

Thanks!

Rich

Rich Callan, MPH

Environmental Health Scientist

Health Research and Fellowships Division

National Center for Environmental Research

Office of Research and Development

U.S. Environmental Protection Agency

Phone: 703-347-8051 Fax: 703-347-8140

Office Address for FedEx, Express Mail or Courier:

US EPA, 2777 South Crystal Drive (Potomac Yard One), Room S-11363, Arlington, VA 22202

Mailing Address (can take a month for delivery): 1200 Pennsylvania Avenue NW, Mail Code 8723P,

Washington, D.C. 20460-0001

Pamela Maxson Callan, Richard

To: Subject: Date:

RE: 1081 - [IRB]Notice of Approved Renewal Tuesday, August 13, 2013 11:53:58 AM

Hi Rich,

I've done some investigating. This is all we get because it is on the university side not the med center

There is no downloadable acceptance.

D

Pamela J. Maxson, Ph.D., SPHR Research Director, Director of Human Resources Children's Environmental Health Initiative Box 90328, A137 LSRC Duke University (919) 812-8389 pm12@duke.edu

From: Callan, Richard [Callan.Richard@epa.gov] Sent: Tuesday, August 13, 2013 10:40 AM

To: Pamela Maxson

Subject: RE: 1081 - [IRB]Notice of Approved Renewal

Hi Pam,

Well yes, could you please see if there is anything else available? This one doesn't seem to provide much detail. But if that is all that is customarily sent now, we'll accept it, it just seems different from the ones I have seen in the past.

Rich			

Rich Callan, MPH
Environmental Health Scientist
Health Research and Fellowships Division
National Center for Environmental Research
Office of Research and Development
U.S. Environmental Protection Agency
Phone: 703-347-8051 Fax: 703-347-8140

From: Pamela Maxson [mailto:pamela.maxson@duke.edu]

Sent: Tuesday, August 13, 2013 10:33 AM

To: Callan, Richard

Subject: FW: 1081 - [IRB]Notice of Approved Renewal

This is the same approval - we don't usually get pdfs anymore since it is electronic. Do you want me to see if I can get one?

Pamela J. Maxson, Ph.D., SPHR Research Director, Director of Human Resources Children's Environmental Health Initiative Box 90328, A137 LSRC Duke University (919) 812-8389 pm12@duke.edu

From: Claire Osgood

Sent: Tuesday, August 13, 2013 9:47 AM

To: Pamela Maxson

Subject: FW: 1081 - [IRB]Notice of Approved Renewal

From: IRB ADMINISTRATOR [mailto:ors-info@duke.edu]

Sent: Monday, September 17, 2012 4:22 PM

To: Marie Miranda (mmiranda); Claire Osqood; Brian Neelon; Pamela Maxson, Ph.D.; Reiter, Jerry;

Myers, Evan ; Ben Strauss Cc: Holly Williams-Stafford

Subject: 1081 - [IRB]Notice of Approved Renewal

Protocol: [1081] Mapping Disparities in Birth Outcomes

Researcher(s):

Evan Myers(Researcher)nullnullnull Claire Osgood(Manager)null Jerry Reiter(Research Staff)null Pamela Maxson(Research Staff)nullnullnullnullnull Marie-Lynn Miranda(Researcher)null Benjamin Strauss(Research Staff)null Brian Neelon(Research Staff)

Expiration Date: 9/16/2013

Your request to renew an approved protocol has been approved.

As described in your original notice of Protocol Approval, researchers agree to:

 Secure approval before making any changes to the protocol, such as adding another subject population, revising procedures, modifying the informed consent process, or replacing or adding investigators.

The form, Request to Amend an Approved Protocol, can be found at: http://www.ors.duke.edu/Research-with-Human-Subjects/forms

Renew the protocol within twelve months.

The form, Request to Renew an Approved Protocol, can be found at: http://www.ors.duke.edu/Research-with-Human-Subjects/forms

- Report any unanticipated risks to the research subjects or deviations from the procedures
 described in the protocol as soon as they are identified. Report to Lorna Hicks at
 lorna.hicks@duke.edu.
- Notify the IRB staff at <u>ors-info@duke.edu</u> when the research is completed.

Pamela Maxson

To:

Callan, Richard

Subject:

Projects A, B, and C approval

Date:

Tuesday, August 13, 2013 10:02:12 AM

Attachments:

24N Auten Approval.pdf DBR IRB.docx

Good morning Rich,

Please find attached and below our current IRB approvals. I will get you the executive summary as soon as possible.

Thanks for all you do,

Pam

Pamela J. Maxson, Ph.D., SPHR Research Director, Director of Human Resources Children's Environmental Health Initiative Box 90328, A137 LSRC **Duke University** (919) 812-8389 pm12@duke.edu

From: eirb@mc.duke.edu [eirb@mc.duke.edu]

Sent: Sunday, May 05, 2013 10:44 AM

To: Pamela Maxson

Subject: eIRB: Continuing review approved



IRB NOTIFICATION OF CONTINUING REVIEW APPROVAL

Continuing Review ID:

CR6_Pro00007633

Principal Investigator:

Geeta Swamy

Protocol Title:

Mapping Disparities in Pregnancy Outcomes: Impact of Psychosocial,

Environmental, and Genetic Factors

Sponsor/Funding Source(s): US Environmental Protection Agency (USEPA)

Federal Funding Agency ID: RD-83329301-0

Date of Declared Concordance with federally funded grant, if applicable: N/A

The Duke University Health System Institutional Review Board for Clinical Investigations has conducted the following activity on the study cited above:

Activity:

Continuing Review

Review Type: Expedited

Review Date:

5/2/2013

Issue Date:

5/3/2013

Anniversary Date:

5/30/2013

Expiration Date:

5/30/2014

DUHS IRB approval encompasses the following specific components of the study:

Protocol, version/date:

Summary, version/date:

--5/22/2012

Consent form reference date:

--closed

Investigator Brochure, version/date:

Pediatric Risk Category:

--45CFR46.404 and 21 CFR 50.51 as applicable

Other:

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study expires at 12 AM on the Expiration Date cited above. At that time, all study activity must cease. If you wish to continue specific study activities directly related to subject safety, you must immediately contact Dr. John Falletta or Jody Power. Continuing review submissions (renewals) must be received by the DUHS IRB office 60 to 45 days prior to the Expiration Date.

No change to the protocol, consent form or other approved document may be implemented without first obtaining IRB approval for the change. Any proposed change must be submitted as an amendment. If necessary in a life-threatening situation, where time does not permit your prior consultation with the IRB, you may act contrary to the protocol if the action is in the best interest of the subject. You must notify the IRB of your action within five (5) working days of the event.

The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB), is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, 21CFR812, and 45CFR164.508-514. In

addition, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization to the extent required by the U. S. Food and Drug Administration.

DUHS Institutional Review Board

2424 Erwin Rd | Suite 405 | Durham, NC | 919.668.5111

Federalwide Assurance No: FWA 00009025

Pamela Maxson Callan, Richard

To: Subject:

SCEDDBO report

Date: Attachments: Wednesday, August 28, 2013 2:16:29 PM SCEDDBO 2013 executive summary.docx

SCEDDBO 2013 3.docx

Hi Rich,

I hope you are well. I have attached the SCEDDBO report as well as the executive summary. I am still looking into the IRB confirmation from Project A. I will keep you informed on that.

Please let me know if there is anything else you need from me.

As always, thanks for all you do.

Warm regards,

Pam

Pamela J. Maxson, Ph.D., SPHR Research Director, Director of Human Resources Children's Environmental Health Initiative Box 90328, A137 LSRC Duke University (919) 812-8389 pm12@duke.edu From: To: Pamela Maxson Callan, Richard

Subject:

question re: SCEDDBO

Date:

Wednesday, October 23, 2013 8:25:20 AM

Attachments: rebudget-3439377.pdf

Good morning Rich,

Welcome back! I am sure you have a million things to do right now and I am sorry to bother you with this. We would like to rebudget a small amount of money (\$5200 direct plus indirects) that is currently on Jerry Reiter's fund code to the parent code. We need your permission in order to do so. I have attached the rebudget for your consideration.

Please let me know if you need anything else from me.

I look forward to seeing you next week.

Thanks,

Pam

Pamela J. Maxson, Ph.D., SPHR Research Director, Director of Human Resources Children's Environmental Health Initiative Box 90328, A137 LSRC Duke University (919) 812-8389 pm12@duke.edu

Pamela Maxson Callan, Richard

To: Subject:

RE: SCEDDBO final report

Date:

Monday, October 06, 2014 1:31:21 PM

Attachments:

SCEDDBO Final Report web.docx

Hi Rich,

I hope that you are doing well and enjoying the beginning of October. I have attached the SCEDDBO final report for the website. I am also copying a link below to our public box site that you can go to and download the figures. I can't attach them to this email because they are too big.

(b) (4)

Best regards,

Pam

Pamela J. Maxson, Ph.D., SPHR Research Director Children's Environmental Health Initiative Box 90328 Duke University (919) 812-8389

From: Pamela Maxson

Sent: Wednesday, July 30, 2014 9:53 AM

To: Callan, Richard

Subject: SCEDDBO final report

Good morning Rich,

Please find attached the SCEDDBO final report. It is in word document but I can format it into a pdf if you would like.

Have a great day,

Pam

Pamela J. Maxson, Ph.D., SPHR Research Director Children's Environmental Health Initiative Box 90328 Duke University (919) 812-8389

Puglisi, Peter Fountain, Joselynn

To: Cc:

Callan, Richard

Subject:

RE: Requesting a Revised SF 425 for EPA Grant RD83329301

Date:

Thursday, January 15, 2015 6:38:26 PM

No, we still need a revised FFR for this grant.

Peter A. Puglisi U.S. Environmental Protection Agency Las Vegas Finance Center (702) 798-2426 (702) 798-2423 (Fax)

You can now email any documents to LVFC-grants@epa.gov in lieu of fax or mail.

Visit our Website at: http://www.cpa.gov/ocfo/finservices/payinfo.htm

From: Fountain, Joselynn

Sent: Wednesday, January 14, 2015 9:03 AM

To: Puglisi, Peter Cc: Callan, Richard

Subject: FW: Requesting a Revised SF 425 for EPA Grant RD83329301

Hi Peter,

Just wanted to follow up to see if the deobligation of funds and financial reclose-out has been processed.

Thanks,

Joselynn Fountain Grants Management Specialist U.S. EPA, OARM, GIAMD 1200 Pennsylvania Ave NW, MC 3903R Washington, DC 20460

Office: 202-564-5305 Fax: 202-565-3082

From: Gombarcik, James

Sent: Monday, December 29, 2014 9:17 AM

To: Leigh Anne Petty; Heather Quadlin; Heather Quadlin **Cc:** Callan, Richard; Fountain, Joselynn; Puglisi, Peter

Subject: RE: Requesting a Revised SF 425 for EPA Grant RD83329301

Leigh Anne,

(b) (4), (b) (6)

Please contact me so that we can resolve the de-obligation of funds and financial re-close of this grant.

Thanks, Jim

James K. Gombarcik
Financial Specialist
US EPA, Las Vegas Finance Center
4220 S. Maryland Pkwy, Bldg C, Rm 503
Las Vegas, NV 89119
(702) 798-2457, fax (702) 798-2423
gombarcik james@epa.gov

Org Email: lvfc-grants@epa.gov
EPA Financial Website: http://www.epa.gov/financial/

From: Leigh Anne Petty [mailto:leighanne.arnold@duke.edu]

Sent: Monday, December 29, 2014 6:02 AM

To: Gombarcik, James; Heather Quadlin; Heather Quadlin Cc: Callan, Richard; Fountain, Joselynn; Puglisi, Peter

Subject: RE: Requesting a Revised SF 425 for EPA Grant RD83329301

Good morning, Jim.

(b) (4), (b) (6)

Thank you for your help, Leigh Anne

Leigh Anne Petty Research Administrative Manager Sponsored Programs Duke University P. O. Box 104004 Durham, N.C. 27705 phone: (919)668-5864

fax: (919)684-8377

From: Gombarcik, James [mailto:gombarcik.james@epa.gov]

Sent: Tuesday, December 23, 2014 5:14 PM

To: Heather Quadlin; Heather Quadlin; Leigh Anne Petty Cc: Callan, Richard; Fountain, Joselynn; Puglisi, Peter

Subject: FW: Requesting a Revised SF 425 for EPA Grant RD83329301

Heather,

We will need (b)(4)

a revised FFR in order to de-obligate the funds and financially re-close the grant. The attached untitled pdf file contains the previous SF 425 that was submitted in August of this year. Please contact me if you need any assistance in preparing the revised document.

Happy holidays to you and yours.

Jim

James K. Gombarcik Financial Specialist US EPA, Las Vegas Finance Center 4220 S. Maryland Pkwy, Bldg C, Rm 503 Las Vegas, NV 89119 (702) 798-2457, fax (702) 798-2423 gombarcik.james@epa.gov

Org Email: lyfc-grants@epa.gov

EPA Financial Website: http://www.cpa.gov/financial/

From: EZTech_Printer [mailto:EZTek@epa.gov] Sent: Tuesday, December 23, 2014 2:02 PM

To: Gombarcik, James

Subject:

From: To: Marie Lynn Miranda mlmirand@umich.edu

Subject:

Sharing News

Date:

Thursday, March 12, 2015 12:09:37 AM

Attachments:

image001.png

Dear Colleagues,

I write to share the news that I have accepted an offer to become the next Provost of Rice University, effective 1 July 2015. You may read Rice's official announcement at www.rice.edu. I am excited about this unexpected opportunity, but will sorely miss the University of Michigan. SNRE and U-M are perfectly aligned with my personal mission and values in so many ways, making this an especially difficult decision.

As I take on the new challenges and opportunities before me, I am deeply grateful for the inspiration and lessons that I have gleaned from all of you. Thank you for your support and collegiality throughout my career.

I hope you will come visit me in Houston.

With my very best regards,

mlm

Marie Lynn Miranda, PhD

Professor and Samuel A. Graham Dean, School of Natural Resources and Environment Director, Children's Environmental Health Initiative
Professor, Departments of Pediatrics and Obstetrics & Gynecology
440 Church Street
2046 Dana Building
Ann Arbor, MI 48109
734.764.2550
mlmirand@umich.edu

